

K122361

FEB 22 2013

**510(k) SUMMARY**

**Tandem Diabetes Care, Inc.'s t:connect Data Management System**

**Submitter's Name:** Tandem Diabetes Care, Inc.  
**Address:** 11045 Roselle Street, Suite 200  
San Diego, California 92121  
Phone: (858) 366-6963  
Facsimile: (858) 202-6707

**Contact Person:** Nora C.R. York  
**Contact Email Address:** nyork@tandemdiabetes.com

**Date Prepared:** July 31, 2012

**Common or Usual Name / Classification Regulation**

The t:connect Data Management System is an accessory to the Tandem t:slim Insulin Pump system which is classified under 21 C.F.R. 880.5725, Pump, Infusion, Insulin, Class II, Product Code, LZG.

**Predicate Devices**

Medtronic MiniMed Diabetes Data Management System (K032164)  
Aidera Diasend System (K101806)

**Intended Use / Indications for Use**

The t:connect Diabetes Management Application is intended for use by individuals with diabetes mellitus who use Tandem Diabetes Care insulin pumps, their care givers, and their healthcare providers in home and clinical settings. The t:connect Application supports diabetes management through the display and analysis of information downloaded from Tandem Diabetes Care insulin pumps and specified blood glucose meters.

**Device Description**

The Tandem t:connect is a web based software system which allows pump users, care givers and healthcare professionals to view data retrieved from a Tandem Ambulatory Insulin Pump and Blood Glucose meters. t:connect is comprised of a Data Uploader, a Web Application, a Secure Web and Database Server, and an Admin Web Application.

The t:connect Data Uploader is a client based software application installed on the pump user's personal computer. Using a USB cable connecting the pump to a personal computer, the application uploads pump data to a secure online database server through a secure, encrypted, internet connection. The t:connect Data Uploader also uploads data from a limited set of Blood Glucose meters.

The t:connect Web Application is a reporting application that provides users with the ability to view and print (to PDF) both tabular and graphical reports representing the data uploaded to the online database. The t:connect Web Application is the "t:connect Website" shown in Figure 1.

The t:connect Web and Database Server is an application that runs on the secure server. Data displayed on the t:connect Web Application is retrieved from the secure Database

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"intermediary" providing an extra layer of security and restricted access to the Database Server.

For both the Data Uploader and the Web Application, users are authenticated against a "pump and patient" database to insure maximum security and secure access to only their data.

The *Admin Web Application* is an application used to manage accounts. It also allows holders of certain types of accounts to *Logon As User* to the *t:connect* Web Application as other users.

*t:connect* does not have the ability to modify any therapy provided by or parameters internal to the devices it communicates with. *t:connect* only reads data from these devices.

The major functions of the device include:

- Retrieve History Log data from the pump and transmit to the database server
- Retrieve History Log data from various BG meters and transmit to the database server
- Retrieve Diagnostic information from the pump and transmit to the database server
- Provide a means to view the pump's complete history log
- Retrieve Pump Settings from the pump for easy viewing by the user
- Display Therapy Data textually and graphically
- Manage User Accounts for retrieving and viewing pump data
- Generate *Notifications* for the user
- Print reports to PDF
- Export data for use in generating customer reports using other software applications
- Provision of user help
- Administrator functionality related to creation and managing user accounts

#### Performance Data

Tandem has completed the necessary performance testing to verify that the design input requirements have been met. Software verification and validation testing was completed to demonstrate the *t:connect* Data Management System meets the established design inputs and its intended use.

1. Software Validation Report
2. Software Verification Report
3. GUI Verification Test Report
4. Human Factors Research Validation Report
5. Software V&V Report
6. Labeling Verification Test report
7. Final Traceability Report
8. Risk Management Summary

#### Clinical and Human Factors Evaluation

Tandem completed three formative human factors studies and a summative human factors validation test using 30 participants. Data from these formative studies were used to refine the graphical user interface of the *t:connect* Data Management System. A summative human factors validation test was completed with 30 participants.

A total of 30 representative adult users stratified into two population segments: (15) healthcare professionals and (15) type 1 diabetics. The participants completed a set of representative task scenarios presented to them in as efficient and timely a manner as

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possible. They were asked to provide feedback regarding the usability and acceptability of the t:connect software system. Participants received 30 minutes of training prior to the session from a Certified Diabetes Educator.

The participant's interaction with the system was observed by the moderator seated in an observation room and were audio/video-recorded using the Morae usability software suite, which captured participant facial gestures and speech, as well as system interaction and data-logging. The Summative study did not reveal any safety related issues.

#### Assurance Case Reports

Tandem has demonstrated the t:connect Data Management System is safe and effective as intended, through the use of *Assurance Case Reports*.

#### Substantial Equivalence

The t:connect Data Management System is as safe and effective as the Medtronic MiniMed Diabetes Data Management System (K032164) and the Aidera Diasend System (K101806), as demonstrated by performance data and equivalence analysis. It has the same intended use/indications for use, and similar technological characteristics and principles of operation, and the minor technological differences between the t:connect Data Management System and its predicate devices raise no new issues of safety or effectiveness. Thus, the t:connect Data Management System is substantially equivalent to the predicate devices.

#### Comparison of Technological Characteristics

Element of Comparison	Tandem Diabetes <i>t:connect</i>	Medtronic <i>DMS</i> (K032164)	Aidera <i>Diasend</i> (K101806)
Application Type	Web App	Web App	Web App
Pie Charts of BG & Insulin	Yes	Yes	Yes
Modal Day BG Charts	Yes	Yes	Yes
Charts of Basal & Bolus Delivery	Yes	Yes	Yes
User Selectable Date Ranges	Yes	Yes	Yes
Logbook	Yes	Yes	Yes
Displays Device Settings	Yes	Yes	Yes
"Print Report" Option	Yes	Yes	Yes
Allows User to Annotate Therapy Data	Yes	Yes	Yes
Dashboard Summary	Yes	No	No
Notifications	Yes	No	No
Exports to Excel Compatible Files	Yes	Yes	Yes
Supported Insulin Pumps	Tandem	Medtronic	Multiple

Element of Comparison	Tandem Diabetes <i>t:connect</i>	Medtronic <i>DMS</i> (K032164)	Aiedera <i>Diasend</i> (K101806)
Supports J&J/LifeScan BG Meters	Yes	Yes	Yes
Supports Abbott BG Meters	Yes	Yes	Yes
Supports Roche BG Meters	Yes	Yes	Yes
Supports Additional BG Meters	No	Yes	Yes
Supports Microsoft OS	Win XP Win Vista Win 7	Win XP Win Vista Win 7	Win XP Win Vista Win 7
Supports Apple Mac OS	OSX 10.5 OSX 10.6 OSX 10.7	OSX 10.5 OSX 10.6 OSX 10.7	OSX 10.5 OSX 10.6 OSX 10.7
Supported Browsers	IE Safari Firefox Chrome	IE Safari Firefox	510(k) Does Not Specify



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

February 22, 2013

Ms. Nora C.R. York  
Tandem Diabetes Care, Incorporated  
11045 Roselle Street Suite 200  
SAN DIEGO CA 92121

Re: K122361  
Trade/Device Name: Tandem t: connect Data Management System  
Regulation Number: 21 CFR 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: LZG  
Dated: February 12, 2013  
Received: February 13, 2013

Dear Ms. Nora C.R. York:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", written over a stylized graphic that resembles a mountain range or a series of peaks.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if known): K122361

Device Name: **Tandem t:connect Data Management System**

## Indications for Use:

The t:connect Diabetes Management Application is intended for use by individuals with diabetes mellitus who use Tandem Diabetes Care insulin pumps, their caregivers, and their healthcare providers in home and clinical settings. The t:connect Application supports diabetes management through the display and analysis of information downloaded from Tandem Diabetes Care insulin pumps and specified blood glucose meters.

Prescription Use

X

(Part 21 CFR 801  
Subpart D)

AND/OR

Over-The-Counter Use

            
(21 CFR 801 Subpart  
C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman  
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**(Division Sign-Off)**  
**Division of Anesthesiology, General Hospital**  
**Infection Control, Dental Devices**

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Division of  
Anesthesiology  
Infection Control

510(k) Number

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